Buprenorphine/Naloxone Pediatric Ingestion: Exposure Rates Differ between Film and Tablet Formulations

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Summary

The purpose of this study it to evaluate whether differences in the rates of unintentional pediatric exposures to buprenorphine and buprenorphine/naloxone formulations are stable over time.

Background

Unintentional exposures to potent opioid medications by young children can cause severe illness or death.

An oral film formulation of buprenorphine/naloxone was introduced for sale in the US in September 2010. A previously published report showed differences in the pediatric exposure rates between the buprenorphine tablet, buprenorphine/naloxone tablet, and buprenorphine/naloxone film formulations, but at the time of the previous study only 18 months of exposure data were available for the combination film.

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Methods

The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System Poison Center program collects data about opioid medication exposures, including patient age, reason for exposure, specific formulation, and medical outcome.

In the first quarter of 2013, 49 poison centers covering 92.6% of the US population provided data to the RADARS System.

Prescription fulfillment data were obtained from IMS Health Solutions.

Data Source

The RADARS System Poison Center program case counts and medical outcomes for unintentional exposures to buprenorphine/naloxone tablets and oral film among children aged 0 – 5 years from October 2009 to March 2013 were analyzed.

To account for drug availability, rates were standardized using unique recipients of a dispensed drug (URDD) per year-quarter.

Negative binomial regression was used to estimate rates and account for drug availability, rates were standardized using unique recipients of a dispensed drug (URDD) per year-quarter.

Results

1,695 reports of unintentional exposure to sublingual buprenorphine products were analyzed.

For the overall study period and for each individual quarter, the rate of exposures to combination tablets exceeded the rates for single ingredient tablets and combination film. These relationships remain consistent over 27 months of measurement.

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Conclusion

The rate of unintentional exposures to buprenorphine/naloxone sublingual film by young children remains significantly less than the rate of exposure to buprenorphine/naloxone or buprenorphine single ingredient tablets.

Participating Poison Centers and Investigators

Buprenorphine Mono-Ingredient Tablets

Combination Tablets

Single Ingredient Tablets

Combination Film

Funding / Disclosures

Because of voluntary reporting, not all exposure cases are known to poison centers.

Formulation identification and reason for exposure are based on information provided by the caller and cannot be verified independently.

These data do not include generic buprenorphine/naloxone tablets, which were introduced in February, 2013.

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